

§ 226.115

§ 226.115 Complaint files.

Records shall be maintained for a period of 2 years of all written or verbal complaints concerning the safety or efficacy of each Type A medicated article(s). Complaints shall be evaluated by competent and responsible personnel and, where indicated, appropriate action shall be taken. The record shall indicate the evaluation and the action.

PART 250—SPECIAL REQUIREMENTS FOR SPECIFIC HUMAN DRUGS

Subpart A—Drugs Regarded as Misbranded

Sec.

250.11 Thyroid-containing drug preparations intended for treatment of obesity in humans.

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250.100 Amyl nitrite inhalant as a prescription drug for human use.

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250.105 Gelsemium-containing preparations regarded as prescription drugs.

250.106-250.107 [Reserved]

250.108 Potassium permanganate preparations as prescription drugs.

Subpart C—Requirements for Drugs and Foods

250.201 Preparations for the treatment of pernicious anemia.

Subpart D—Requirements for Drugs and Cosmetics

250.250 Hexachlorophene, as a component of drug and cosmetic products.

AUTHORITY: 21 U.S.C. 321, 336, 342, 352, 353, 355, 361(a), 362(a) and (c), 371, 375(b).

SOURCE: 40 FR 14033, Mar. 27, 1975, unless otherwise noted.

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Subpart A—Drugs Regarded as Misbranded

§ 250.11 Thyroid-containing drug preparations intended for treatment of obesity in humans.

(a) Investigation by the Food and Drug Administration has revealed that a large number of drug preparations containing thyroid or thyrogenic substances in combination with central nervous system stimulants, with or without one or more additional drug substances such as barbiturates or laxatives, are being marketed for or as adjuncts to the treatment, control, or management of obesity in humans. The Commissioner of Food and Drugs finds that the administration of such combinations for said purposes is without medical rationale except possibly in those relatively uncommon instances where the condition is directly related to hypothyroidism and there exists a concurrent need for appetite control (in such instances the safety and effectiveness of such combinations are not generally recognized). In particular, the Commissioner of Food and Drugs finds that neither the consensus of informed medical opinion nor clinical experience justifies any representation that such combinations are safe and effective in connection with the treatment, control, or management of obesity in patients having normal thyroid function.

(b) Combinations of thyroid or other thyrogenic drugs with central nervous system stimulants with or without other drug substances when offered for or as adjuncts to the treatment, control, or management of obesity not related to hypothyroidism are regarded as misbranded. Such combinations when offered for obesity in humans directly attributable to established hypothyroidism are regarded as new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act.

§ 250.12 Stramonium preparations labeled with directions for use in self-medication regarded as misbranded.

(a) Stramonium products for inhalation have been offered for use in the